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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,765	EGNELOV ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-14,16-18 and 20* is/are rejected.

7)☒ Claim(s) *9,15 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/18/04,1/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the inner seal claimed on lines 2-3 of claim 17, the locking member claimed on lines 3-5 of claim 17, and the insertion tube claims on lines 8-10 of claim 17 must be shown or the feature(s) canceled from the claim(s). The window of the body portion claimed on lines 1-2 of claim 19 must also be shown or the feature must be cancelled from the claim. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification lacks sufficient support for a system for sealing a percutaneous wound in a blood vessel comprising both a window in the body portion, as claimed in claim 19, and another window of the indicator device, as claimed on lines 16-18 of claim 17, upon which claim 19 depends. The specification does show such a system wherein there is a single window 20 on the body portion which functions as the window of the indicator device (fig. 1 of the instant specification), but fails to show such a system having two windows, as claimed.

The specification further lacks sufficient antecedent basis for a device wherein the duct becomes narrower in the direction towards the blood accommodating chamber, as claimed in claim 9, or wherein the duct widens in the direction towards the blood accommodating chamber, as claimed in claim 10. Figs. 7-9 show alternative designs of the duct, but there is no description of the shape of the duct with respect to the blood accommodating chamber.

Claim Objections

Claim 17 is objected to because of the following informalities: on line 4 of the claim, "puncture" should be replaced with "wound". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 13, 14, 16, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,193,670 to Van Tassel et al. Van Tassel discloses an indicator device for visually indicating a blood pressure comprising a body (figs. 1-3 of Van Tassel), the body comprising a duct 32 extending in the body and having a sealed proximal end (figs. 1-3; col. 5, lines 32-41 of Van Tassel). A distal end portion 16 of the body is adapted to be positioned inside a blood vessel and comprises a liquid inlet opening 50, 52, 54 in fluid communication with the duct 32 (figs. 3 & 5; col. 5, lines 53-63; col. 6, lines 3-10 of Van Tassel). A window 46 comprises an at least semi-transparent section configured to enable visual observation of blood entering the duct 32 via the inlet opening 50, 52, 54 when the inlet opening 50, 52, 54 is located inside the blood vessel (fig. 1 & 5; col. 6, lines 11-30 of Van Tassel).

Regarding claims 2-7, the sealed proximal end comprises a blood accommodating chamber 44 (figs. 2 & 3; col. 5, lines 32-41; col. 6, lines 11-29 of Van Tassel).

Regarding claims 3, 14, and 16, the duct 32 opens into the chamber 44 via an aperture 38, 42 having a spill-over edge, the aperture being located at a level above a bottom surface of the blood accommodating chamber 44, whereby return flow of the blood back into the duct 32 is prevented (figs. 1-3 of Van Tassel). With further regard to claims 14 and 16, the blood accommodating chamber 44 and the duct 32 are dimensioned such that a counter-pressure therein when blood enters will cause a blood

meniscus at a lowest possible systolic pressure to be located within the window 46 (fig. 1; col. 6, lines 26-29 of Van Tassel). With further regard to claim 16, since the configuration of the meniscus is formed based on the direction of gravity, the configuration of the meniscus with regard to the direction of flow in the duct is regarded as "intended use" language, which cannot be relied upon to define over the prior art of Van Tassel, since the prior art reference teaches all of the claimed elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The device of Van Tassel can be positioned such that the direction of flow is perpendicular to the meniscus.

Regarding claims 4 and 5, the blood accommodating chamber 44 is located in the body of the device and the body of the device further comprises an insertion tube 12 which may extend distally of the body (figs. 1-3 of Van Tassel). With further regard to claim 5, the inlet opening 50, 52, 54 is located on the insertion tube 12 (figs. 2 & 4 of Van Tassel).

Regarding claim 6, the duct 32 extends vertically to an aperture 38, 42 opening into the blood accommodating chamber 44 (figs. 2 & 5 of Van Tassel).

Regarding claim 7, the duct 32 extends horizontally above the blood accommodating chamber 44 to an aperture opening 38, 42 into the blood accommodating chamber 44 (fig. 1 of Van Tassel).

Regarding claim 13, figures 10-12 of Van Tassel disclose an embodiment of the device in which the duct 146 is helically shaped (figs. 10-12; col. 8, lines 18-29 of Van Tassel).

Regarding claim 20, the indicator device is provided, the distal end portion 16 is positioned inside the blood vessel and the blood pressure is indicated (figs. 1, 5, & 6; col. 6, lines 11-29 of Van Tassel).

Claims 1-8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 3,062,202 to Hyman et al. Hyman discloses an indicator device 10 for visually indicating a pressure of blood inside a blood vessel comprising a body, the body comprising a duct 16, 30 extending into the body and having a sealed proximal end (figs. 2 & 4; col. 1, lines 11-14; col. 2, lines 35-69; col. 3, lines 36-47 of Hyman). A distal end portion 12 is adapted to be positioned inside the blood vessel and comprising a liquid inlet opening in fluid communication with the duct 16, 30 (figs 1 & 4 of Hyman). A window 22, 30 comprises an at least semi-transparent section configured to enable visual observation of blood entering the duct 16, 30 (figs. 2 & 3; col. 2, lines 50-56;col. 3, lines 39-48 of Hyman).

Regarding claims 2-7, the sealed proximal end of the duct 16, 30 comprises a blood accommodating chamber 26, 38 (figs. 2-4; col. 2, lines 61-69; col. 3, lines 48-52 of Hyman).

With further regard to claim 3, the duct 16 opens into the chamber 26 via an aperture having a spill-over edge (figs. 1 & 2), wherein, when the device 10 is held with

distal end portion 12 in a downward direction, the aperture is located at a level above a bottom surface of the chamber 26, whereby return flow to the duct 16 is prevented.

With further regard to claims 4 and 5, the blood accommodating chamber 26, 38is located in the body, and the distal end portion 12 of the body comprises an insertion tube extending distally of the body (figs. 1, 2, & 4 of Hyman). The inlet opening is located on the insertion tube 12 (figs. 1 & 4; col.2, lines 40-44 of Hyman).

With further regard to claim 6, the duct 16 extends vertically to an aperture opening into the blood accommodating chamber 26 (fig. 2 of Hyman).

With further regard to claim 7, when held with the distal end portion 12 in a downward direction, the duct 16 extends horizontally above the chamber 26 to an aperture opening into the chamb26 (fig. 2 of Hyman).

Regarding claims 8 and 12, the duct 16 may exhibit a varying cross-section over its length (col. 3, lines 19-31 of Hyman). With further regard to claim 12, since the window 22 covers both the duct 16 and the chamber 26, in the case where the cross-section of the duct varies, such variation would be within the area of the window 22.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyman, as applied to claims 1-8 and 12, above, and further in view of US Patent

No. 6,485,428 to Enk. Hyman teaches that the cross section of the duct may vary over its length but is silent as to how. However, Enk discloses a fluid filled manometer similar to that of Hyman wherein the cross section of the duct 4 varies such that the duct is narrower at a distal end and wider at a proximal end (figs. 4, 5, and 10; col. 12, line 52- col. 13, 13 of Hyman). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the configuration of the duct of Enk as that of Hyman, since Hyman teaches that a varying cross section may be used, and Enk teaches such a cross section in a manometer, and in order to improve the accuracy and readability of the pressure measuring apparatus (col. 5, lines 26-40 of Enk).

Regarding claim 11, the duct first becomes narrow and then widens (figs. 4, 5, and 10 of Enk).

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel, as applied to claims 1-7, 13, 14, 16, and 20 above, and further in view of US Patent No. 5,342,393 to Stack. Van Tassel describes a system comprising an indicator device as claimed (figs. 1-3 of Van Tassel, see above description of Van Tassel) for sealing a percutaneous puncture in a blood vessel, a body portion 62 having a duct for insertion and extraction of devices to and from an inner region of the blood vessel, and an insertion tube 60 coupled to the body portion and through which the device for sealing the blood vessel is inserted (figs. 4 & 5; col. 5, line 64-col. 6, line 10 of Van Tassel). However, the device of Van Tassel injects a fluid hemostatic agent into the percutaneous puncture in the blood vessel to seal it, rather than using an inner seal and locking member (col. 5, lines 113-15; col. 6, lines31-55 of Van Tassel). Stack discloses

a device for sealing a percutaneous puncture in a blood vessel that uses an inner seal and locking member (col. 1, lines 6-10 of Stack). The device of Stack comprises an inner seal 18 adapted to be positioned against an inner surface of a vessel wall and a locking member 32 connected to the inner seal 18 and adapted to be positioned against an outer surface of the vessel wall, such that the percutaneous wound is sealed therebetween (figs. 3-6; col. 2, lines 40-59 of Stack). An insertion tube 10 is adapted to be inserted into the blood vessel through the wound and the inner seal 18 may be passed through the tube 10 for deployment inside the blood vessel (figs. 1-3; col. 2, lines 40-43 of Stack). The insertion tube 10 is shown in figures 1 and 2 of Stack to be coupled to a body portion having at least one duct, similar to the insertion tube and body portion of Van Tassel. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use insertion tube, seal, and locking member assembly of Stack in place of the injection assembly of Van Tassel, since the two types of sealing a percutaneous puncture in a blood vessel are shown to be functionally equivalent.

Regarding claim 18, the indicator device is integrated in said body portion (fig. 5 of Van Tassel).

Allowable Subject Matter

Claims 9, 15, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 9, the prior art of record fails to teach or fairly suggest a blood pressure indicator device comprising a body comprising a duct wherein the sealed proximal end of the duct comprises a blood accommodating chamber, and wherein the duct becomes narrower in the direction towards the blood accommodating chamber, and in combination with all of the other limitations of the claim.

Regarding claim 15, the prior art of record fails to teach or fairly suggest a blood pressure indicator device comprising a blood accommodating chamber and duct dimensioned such that a counter-pressure therein, when blood enters, will cause a blood meniscus at a lowest possible systolic pressure to be located approximately at the spill-over edge.

Regarding claim 19, the prior art of record fails to teach or fairly suggest a system for sealing a percutaneous wound in a blood vessel comprising a body portion comprising a window through which blood can be visually observed and an indicator device comprising an indicator body, the indicator body comprising a window in the form of an at least semi-transparent section configured to enable visual observation of blood entering into the indicator duct, and in combination with all of the other limitations of the claim.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,794,485 to Shalaby et al.

US Patent No. 5,620,461 to Muijs Van De Moer et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
Patent Examiner
Art Unit 3736